

REMARKS

Claims 42-73 are now active in this application. Support for these claims is found in Claims 1-41 in the specification as originally filed. A substitute Sequence Listing is provided to clarify the sequence in SEQ ID NO:3 corresponding to the sequence for the beta 2 toxin gene promoter of type C *Clostridium perfrigens*. Support for this change is found in the specification on page 17, lines 10-16 and nucleotides 1-267 in SEQ ID NO:1.

Applicants have now submitted a substitute Sequence Listing and a corresponding computer-readable Sequence Listing. The sequence information recorded in the corresponding computer-readable Sequence Listing is identical to the paper copy of the substitute Sequence Listing. Support for all of the sequences listed in the substitute Sequence Listing is found in the present application as originally filed.

No new matter is believed to have been added.

Applicants wish to thank Examiner Portner for the helpful and courteous discussion granted to the Applicants' undersigned representative on August 8, 2002. During this discussion the issue of priority was discussed. In particular, the Applicants' undersigned representative noted that the Applicants would be filing certified copies of the PCT and French priority documents to perfect priority. Applicants' undersigned representative further noted that the French Priority document had already been filed on October 2, 2000. In addition, claim amendments were discussed to address the rejections under 35 U.S.C. § 112 and 35 U.S.C. § 102. These amendments are believed to be reflected in the claims submitted herein. Therefore, in view of this discussion, the amendments submitted herein, and the following remarks, favorable reconsideration and allowance of all pending claims is kindly requested.

Applicants affirm the election of Group I, with traverse. Pending Claims 42-73 are

drawn to this elected group.

A copy of all pending claims is provided herein.

With respect to the Examiner's request for clarification of all SEQ ID NO:2 as noted in the figure legend for Figure 8, this sequence is in fact SEQ ID NO:2 however due to its size, the Figure was provided on two pages, thus yielding Figures 8A and 8B. For clarification, Applicants have amended the specification to reflect the presence of Figures 8A and 8B corresponding to the two parts of this Figure.

Turning to the issue of priority raised on pages 4-5 of the Official Action, Applicants submit herewith certified copies of PCT/FR98/0199 which was filed on September 17, 1998, and French application 971170 filed September 19, 1997, which had previously been submitted to the Office on October 2, 2000. Therefore, in accordance with Applicants Request for Priority filed on March 20, 2000 Applicants request benefit of the filing date of International Application PCT/FR98/0199 under the provisions of 35 U.S.C. § 120 and right of priority to French Application 9711710 filed on September 19, 1997 under the provisions of 35 U.S.C. § 119.

Applicants further note that the 30 month priority date, which was March 19, 2000, was a Sunday and as such the present application was filed on the next business day, Monday, March 20, 2000. March 20, 2000 was not a Thursday and invite the Examiner to refer to the attached calender from the year 2000.

The rejection of Claims 1-3 and 19 under 35 U.S.C. § 101 is believed to have been obviated by amendment.

The rejection of Claim 1 and 9-11 under the doctrine of obviousness-type double patenting over Claims 1-2 of U.S. Patent Number 5,874,220 is obviated by amendment.

With respect to the pending claims, as submitted herein, this rejection is respectfully

traversed.

The present claims are drawn to a purified nucleic acid comprising a sequence with transcriptional promoter activity, e.g., the promoter sequence of the beta 2 toxin gene of *C. perfringens* or a sequence which encodes a secretion signal peptide as in Claim 60. However, the claims of U.S. Patent Number 5,874,220 are directed to nucleic acids of SEQ ID NO:27 which encode the actual protein itself, i.e., the *C. perfringens* beta 2 toxin, in the present application the coding region of the beta 2 toxin from nucleotides 268 to 1062 in SEQ ID NO:1, whereas the promoter sequence is nucleotides 1 to 267 in SEQ ID NO:1, which is also listed separately in SEQ ID NO:3. In addition, it is noted that Claims 1 and 2 of U.S. 5,874,220 nucleic acid consisting of a nucleic acid sequence and thus are directed to sequences which do not include sequences upstream or downstream of SEQ NO ID:27.

Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claims 1-17, 19, 24, 26-37 under 35 U.S.C. § 112, first paragraph ("written description") is obviated by the cancellation of these claims.

With respect to pending Claims 42-73 this rejection is respectfully traversed.

As noted in the sequence listing the specification does provide the sequence SEQ ID NO:3.

The specification defines the terms "portion" and "fragment" on the paragraph bridging pages 4-5 of the present specification.

The term "hybridizing" is defined in lines 4-17 of the specification on page 5.

On page 5, lines 18-24 Applicants describe how to determine transcriptional promoter activity, for example, as recited in last line of Claim 42 (see also the specification on pages 17-20 for additional description of transcriptional promoter activity).

The term "toxin" this is defined in the paragraph bridging pages 6-7.

Therefore, the claims are deemed to be adequately described under the meaning of 35 U.S.C. § 112, first paragraph and as such withdrawal of this ground of rejection is kindly requested.

The rejection of Claims 1-8, 10-11, 14-17, 24, 26-27 and 35-37 under 35 U.S.C. § 112, second paragraph is believed to have been obviated by amendment.

As noted in the preceding paragraph "transcriptional promoter activity", "portion", "variant", are defined in the specification on pages 4-8.

The term transgene is a well known term of art, for example, see the attached entry from the online edition of Merriam-Webster's Medical Dictionary.

Withdrawal of this ground of rejection is respectfully requested.

The rejection of Claims 14 and 16-17 under 35 U.S.C. § 112, second paragraph is obviated by amendment.

The rejection of Claim 15 under 35 U.S.C. § 112, second paragraph is obviated by amendment.

The rejection of Claims 1-17, 19, 24, and 26-37 under 35 U.S.C. § 102(b) over Gilbert et al. (Gene, December 5, 1997) is obviated by the cancellation of these claims.

The publication date of Gilbert et al. is December 5, 1997. The present application was filed on March 20, 2000 as a Continuation application of PCT/FR98/01999 filed on September 17, 1998, which in turn claims priority to French Application 971170 filed on September 19, 1997. In view of the attached certified copies of the PCT application and the French priority document, Applicants request that the Office acknowledge Applicants' request for priority and also withdrawal of this rejection.

The rejection of Claims 1, 4, 7-8, 9-13, 14-17, 24, and 26-37 under 35 U.S.C. § 102(e) over Johnson et al. (U.S. Patent Number 5,955,368) is obviated by the cancellation of

these claims.

Johnson et al. was filed on April 6, 1998 and issued on September 21, 1999. The present application was filed on March 20, 2000 as a Continuation application of PCT/FR98/01999 filed on September 17, 1998, which in turn claims priority to French Application 971170 filed on September 19, 1997. In view of the attached certified copies of the PCT application and the French priority document, Applicants request that the Office acknowledge Applicants' request for priority and also withdrawal of this rejection.

The rejection of Claim 1 under 35 U.S.C. § 102(b) over WO 97/37685 (October 16, 1997) is obviated by the cancellation of this claim.

The publication date of this reference is October 16, 1997. The present application was filed on March 20, 2000 as a Continuation application of PCT/FR98/01999 filed on September 17, 1998, which in turn claims priority to French Application 971170 filed on September 19, 1997. In view of the attached certified copies of the PCT application and the French priority document, Applicants request that the Office acknowledge Applicants' request for priority and also withdrawal of this rejection.

The rejection of Claim 19 under 35 U.S.C. § 102(b) over Draper et al. (U.S. Patent Number 5,693,535) is obviated by the cancellation of this claim.

Claim 60 as submitted herein recites:

A purified nucleic acid comprising SEQ ID NO:4 or a portion of SEQ ID NO:4, which encodes a peptide that functions as a secretion signal peptide.

Draper et al disclose a sequence that has 11 nucleotide similarity to SEQ ID NO:4. However, nowhere in Draper et al is there a disclosure or a suggestion for those portions of SEQ ID NO:4, which encode a peptide that functions as a secretion signal peptide.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of Claim 1 under 35 U.S.C. § 102(b) over WO 96/30043 is obviated by the cancellation of this claim.

This prior art reference discloses a nucleotide sequence that has a 15 nucleotide identity with SEQ ID NO:3. However, this reference provides no disclosure for a portion or variant of SEQ ID NO:3 which has transcriptional promoter activity as required in the present claims.

Therefore, withdrawal of this ground of rejection is requested.

The rejection of Claim 1 under 35 U.S.C. § 102(b) over WO 91/18997 is obviated by the cancellation of this claim.

WO 91/18997 discloses a nucleotide sequence that has a 13 nucleotide identity with SEQ ID NO:3. However, this references provides no disclosure for a portion or variant of SEQ ID NO:3 which has transcriptional promoter activity as required in the present claims.

Accordingly, withdrawal of this ground of rejection is requested.

In view of the above, Applicants submit that the present application is now ready for allowance. Early notification of such allowance is kindly requested.

Respectfully submitted,
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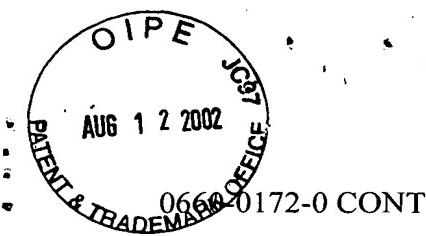


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AUG 15 2002

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Marked-Up Copy
Serial No: 09/531,438
Amendment Filed on: HEREWITH

IN THE SPECIFICATION

Please amend the specification as follows:

Page 1, between lines 2 and 3, please insert the following:

--CROSS-REFERENCE TO A RELATED APPLICATION

The present application is a Continuation of PCT/FR98/01999, which was filed on September 17, 1999.--

Page 14, line 29, please replace the text with the following:

[Figure 8] Figures 8A and 8B: Hydrophobicity profile for beta2 toxin (SEQ ID NO:2).

Page 28, after last line, beginning on a new page, please replace the Sequence Listing filed on March 23, 2001, with the attached substitute Sequence Listing.

IN THE CLAIMS

1-17. (Canceled).

19. (Canceled).

21-22. (Canceled).

24-41. (Canceled).

42-73. (New).